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JAN 26 2012

Concurrence of CDRH, Office of Device Evaluation (ODE)

Appendix I

510(k) Summary

As required by 21 CFR 807.87(h), a 510(k) Summary for this Premarket Notification submission is provided below.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

PHILIPS

CAlg-STR Exercise ECG Analysis Algorithm

Submitter's Name and Address

Submitter's Name:	Philips Healthcare
Division:	Diagnostic ECG
Address:	1525 Rancho Conejo Boulevard Suite 100
City, State, and Zip:	Thousand Oaks, CA 91320
Contact Name:	Gretel Lumley/Quality and Regulatory Engineer
Telephone / Fax:	(805) 214-5101 / (805) 214-5129

Manufacturers' Information: Establishment Registration Number

Establishment name:	Philips Medical Systems
Address:	3000 Minuteman Road Andover, MA 01810
Establishment Registration No.	1218950

Device Details

	New Product	Predicate
Proprietary or Trade Name:	CAlg-STR Exercise ECG Analysis Algorithm	Case Cardiac Testing Sytem/CS Cardiac Testing System
Common Name:	ECG Analysis System	ECG Analysis Computer
Device Class:	II	II
Device ProCodes:	DPS	DQK
Device CFR:	870.2340	870.1245
Classification Panel:	74 Cardiovascular	74 Cardiovascular
Classification Name:	ECG Analysis System	Programmable diagnostic computer

Intended Use

The intended use of the CAlg-STR Exercise ECG Analysis Algorithm is to analyze multi-channel ECG waveforms acquired from a patient and produce measurements such as heart rate, detect ventricular arrhythmias, form representative beats, and calculate ST segment deviation (elevation or depression) and ST slope for review by a trained physician or clinician in determining a diagnosis. The measurements should not be used as a sole means for determining a patient's diagnosis.

Device Description

The CAlg-STR Exercise ECG Analysis Algorithm is a software module which may be integrated into a stress exercise system. It is used to analyze ECG waveforms to find and classify heart beats to calculate heart rate, detect arrhythmias and calculate ST deviation and ST slope when an adult or pediatric patient is undergoing cardiac stress testing.

The exercise ECG Analysis Algorithm takes up to 16 ECG leads as input and provides analysis and measurements. The Exercise ECG Analysis Algorithm analyzes up to 3 leads of ECG waveforms to find and classify the heart beats and calculate heart rate. The beat classifications are then used to calculate arrhythmias. The beats with similar morphology are averaged to from representative beats for up to 16 leads. The representative beats are used to measure ST deviation and slope for up to 16 leads. Those measurements are used for display and report in the host device. The algorithm does not supply an interpretation of the data.

Product Comparison:

Specification / Feature	CAlg-STR Exercise ECG Analysis Algorithm	CASE Cardiac Testing System/CS Cardiac Testing System	Comparison
Indications for Use	**Intended Use:** The intended use of the CAlg-STR exercise ECG analysis algorithm is to analyze mult-channel ECG waveforms acquired from a patient and produce measurements such as heart rate, detect ventricular arrhythmias, form representative beats, and calculate ST segment deviation (elevation or depression) and ST slope for review by a trained physician or clinician in determining a diagnosis. The measurements should not be used as a sole means for determining a patient's diagnosis. **Indications for Use:** The analysis algorithm is indicated for use in those situations where the clinician decides to evaluate the electrocardiogram of patients at 10 years or older, as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment or to rule out causes for symptoms	**Intended Use:** CASE Cardiac Testing System and the CS Cardiac Testing System are intended to be used by trained operators under direct supervision of a licensed health care practitioner on adult and pediatric patients. The CASE Cardiac Testing System and the CS Cardiac Testing System are designed to acquire, process, record, archive, analyze and output (12 and 15 lead) ECG data during a period of physiologic stress or during a resting ECG test, acquire data from ancillary devices (such as Spirometery and Ambulatory Blood Pressure), provide median morphology recordings and record ECG in real-time with and without arrhythmia detection. ***The arrhythmia detection portion of CASE Care provided to the user for the convenience of automatic detection of arrhythmias but does not provide alarms.*** CASE Cardiac Testing System and the CS Cardiac Testing System provide the control of external devices (typically treadmill or Ergometer) and communicate with centralized electronic/digital storage system via network. CASE Cardiac Testing System and the CS Cardiac Testing System provide a user selectable option for printouts of prognostic scores on select reports. Vector loops are also available. Case Cardiac Testing System and the CS Cardiac Testing System can be configured in a network environment for multiple CASE or CS stations allowing the user to create a central database of patient demographics and collected patient physiological data. ***CASE Cardiac Testing System and the CS Cardiac Testing System are intended to be used primarily in the hospital but can be used in clinics, physician offices, outreach centers or wherever exercise, stress testing ECG, Spirometry or ambulatory blood pressure testing is performed.*** ***CASE Cardiac Testing System and the CS Cardiac Testing System offer no diagnostic opinion to the user.*** Instead it provides interpretive statements of morphology, rhythm, and conduction for with the physician renders his/her own medical opinion. CASE/CS Cardiac Testing System is not intended to be used as a transport device or for home use. CASE Cardiac Testing System and the CS Cardiac Testing System are not interceded for the use as a vital signs physiological monitor or for intracardiac use.	Similar for algorithm and use environment.
Target Population	Adult and Pediatric	Adult and Pediatric	Same

Specification / Feature	CAlg-STR Exercise ECG Analysis Algorithm	CASE Cardiac Testing System/CS Cardiac Testing System	Comparison
Where Used	Used in hospital and clinical settings, by qualified medical personnel trained in stress exercise testing.	Used primarily in the hospital but can be used in clinics, physician offices, outreach centers or wherever exercise, stress testing ECG, Spirometry or ambulatory blood pressure testing is performed.	Similar
Display	Displayed on host device	Displayed on host device.	Same
Number of ECG Signal Leads	Up to 16 leads	Up to 16 leads	Same
Sampling Rate	1000 samples per second	500 samples per second	Different
Bandwidth	.050 – 150 Hz	.050 – 150 Hz	Similar
Input Signal Resolution	5μV/LSB at 1000 Hz	4.88μV/LSB at 500 Hz	Similar, Hz difference is due to sampling rate
Notch Filter	Yes, configurable	Yes, Configurable	Same
Baseline Correction	Cubic Spline Algorithm	Cubic Spline Algorithm	Same
Artifact/Baseline Correction	No	Finite Residual Filter (FRF) Analysis	Different, did not implement FRF due to potential distortion of ST segment
ST Measurements and Calculations	ST amplitude, ST Slope	ST amplitude, ST Slope, integral, index, ST/HR slope, ST/HR loops, ST/HR index up to 15 leads	Similar, only ST amplitude and ST slope are calculated other measurements are provided by the host device
Heart Rate	Automatic Arrhythmia detection, documentation and annotation	Automatic Arrhythmia detection, documentation and annotation	Similar
Post J-Point selection	Configurable	Configurable	Same
Biocompatibility	Not applicable	Not applicable	Identical
Sterility	Not applicable	Not applicable	Identical

The CAlg-STR Exercise ECG Analysis Algorithm has same technological characteristics except for the sampling rate and Artifact/Baseline correction as shown in the table above. The difference between the predicate's sampling rate and the CAlg-STR Exercise ECG Analysis Algorithm is not significant because a higher sampling rate creates a better fidelity of the ECG signal that is analyzed. The predicate device chose to include Artifact/Baseline correction which is not included in the CAlg-STR Exercise ECG Analysis Algorithm. Philips Medical Systems chose not to include Artifact/Baseline Correction due to potential distortion of the ST segment which would have potentially

caused decreased accuracy of the algorithm and additional design changes to the algorithm would have been necessary to address distortion of the ST segment.

Performance Data

The performance data demonstrated that the CAlg-STR Exercise ECG Analysis Algorithm meet with the design specifications of the algorithm. The CAlg-STR Exercise ECG Analysis Algorithm was tested to the requirements of ANSI/AAMI/ISO EC57:1988/(R)2008: Testing and reporting performance results of cardiac rhythm and ST-sgement measurement algorithms. The performance results from this testing demonstrated that CAlg-STR Exercise ECG Analysis Algorithm performed consistentlyand meets the requirements of ANSI/AAMI/ISO EC57:1988/(R)2008: Testing and reporting performance results of cardiac rhythm and ST-sgement measurement algorithms.

Conclusions

In conclusion, the performance and non-clinical testing demonstrated that the CAlg-STR Exercise ECG Analysis Algorithm is as safe and effective as the analysis software of the predicate device. This is supported by the adherence to the FDA recognized consenus standard (ANSI/AAMI/ISO EC57:1988/(R) 2008: Testing and reporting performance results of cardiac rhythm and ST-sgement measurement algorithms) and comparison testing to other algorithms already approved for market. .

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 2 6 2012

Philips Healthcare
c/o Ms. Gretel Lumley
1525 Rancho Conejo Blvd, Suite 100
Thousand Oaks, CA 91320

Re: K112959
Trade/Device Name: CAlg-STR Exercise ECG Analysis Algorithm
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: January 10, 2012
Received: January 11, 2012

Dear Ms. Lumley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

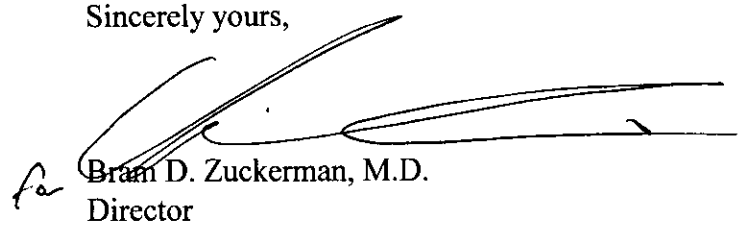
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix H

Indications for Use Statement

510(k) Number: _____
Device Name: **Philips CAlg-STR Exercise Analysis Algorithm**

Indications for Use:

Intended Use:

The intended use of the CAlg-STR exercise ECG analysis algorithm is to analyze multi-channel ECG waveforms acquired from a patient and produce measurements such as heart rate, detect ventricular arrhythmias, form representative beats, and calculate ST segment deviation (elevation or depression) and ST slope for review by a trained physician or clinician in determining a diagnosis. The measurements should not be used as a sole means for determining a patient's diagnosis.

Indications for Use:

The analysis algorithm is indicated for use in exercise ECG testing where the clinician decides to evaluate the electrocardiogram of patients at 10 years or older, as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment or to rule out causes for symptoms. The analysis algorithm is not intended to be used as a physiological monitor.

Prescription Use (21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112959